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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,707	04/27/2000	John Greenwood	19141-002	2553

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EXAMINER

LOEB, BRONWEN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/559,707

Applicant(s)

GREENWOOD ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,10,24 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,10 and 24 is/are rejected.
- 7) ☒ Claim(s) 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/973,553.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 9 December 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/559,707 is acceptable and a CPA has been established. An action on the CPA follows.

It is noted the the CPA filed was not accompanied by any amendments or remarks regarding the outstanding rejections. Therefore, the following action reproduces the maintained and new rejections set forth in the action mailed 7 June 2002.

Claims 1, 10, 24 and 37 are pending.

### ***Claim Objections***

1. Claims 24 and 37 are objected to because of the following informalities:

In amended claim 24, the phrase "the cells of" in line 3 should be deleted as the Markush group recites cell lines.

In claim 37, the word "Institut" is misspelled as "Insitut". It lacks the "t" immediately after the "s".

Appropriate correction is required.

### ***Summary of Outstanding Rejections***

2. Claim 10 stands rejected under 35 USC §112, first paragraph for lack of enablement for reasons of record and as discussed below.

Claim 1 stands rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,361,771 B1 for reasons of record and as discussed below.

Claims 1 and 24 stand rejected under 35 U.S.C. 102(e) as being anticipated by Tao et al (USP 6,361,771 B1) for reasons of record and as discussed below.

### ***Response to Arguments***

3. With regard to the rejection of claim 10 under 35 USC §112, first paragraph, Applicant reiterated in the response filed 20 May 2002 that they will deposit the recited cell lines (hRPE-7 and hRPE-116) upon indication of allowable subject matter. The rejection stands until Applicant deposits the cell lines or makes a statement that such deposits will be made in accordance with 37 CFR §1.803. See MPEP §2411.02.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,361,771 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because an ARPE-19 cell line transformed to express one of BDNF, NT-4, CNTG, Axokine, IGF I or II, TGF $\beta$ -II, Midkine, IL-1 $\beta$ , TNF, NGF, IL-2/3, ILFD, IL-6, NTN, Neublastin, VEGF, GDNF, PDGF, LEDGF or PEDF, which is one embodiment of claim 1, is essentially generic to claim 7 of USP 6,361,771 B1 which claims such a cell line with a semipermeable membrane.

Claim 1 is directed to an invention not patentably distinct from claim 7 of commonly assigned US Patent No. 6,361,771 B1. Specifically, an ARPE-19 cell line transformed to express one of BDNF, NT-4, CNTG, Axokine, IGF I or II, TGF $\beta$ -II, Midkine, IL-1 $\beta$ , TNF, NGF, IL-2/3, ILFD, IL-6, NTN, Neublastin, VEGF, GDNF, PDGF, LEDGF or PEDF, which is one embodiment of claim 1, is essentially generic to claim 7 of USP 6,361,771 B1 which claims such a cell line with a semipermeable membrane.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US Patent No. 6,361,771 B1, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting

inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. §102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. §122(b). Therefore, this application is examined under 35 U.S.C. §102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. §102(e)).

7. Claims 1 and 24 are rejected under 35 U.S.C. §102(e) as being anticipated by Tao et al (USP 6,361,771 B1).

Tao et al teach ARPE-19 comprising an expression vector coding for one of the following polypeptides: BDNF, NT-4, CNTG, Axokine, IGF I or II, TGF $\beta$ -II, Midkine, IL-1 $\beta$ , TNF, NGF, IL-2/3, ILFD, IL-6, NTN, Neublastin, VEGF, GDNF, PDGF, LEDGF or PEDF. The polypeptides may be expressed in vitro by incubating the transformed ARPE-19 cells in appropriate medium. See entire document, especially col. 7, line 50-col. 8, line 65; col. 20, line 4-col. 22, line 10; and claim 7.

### ***Prior Art Made of Record***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Csaky et al (USP 5, 998,598) teaches immunoadhesions which are fusions of, for instance, a cytokine and IgG. Disclosed are IL-1beta, tumor necrosis factor and PDGF. Also disclosed is ARPE-19 which is used to demonstrate that an adenoviral vector encoding one of the fusions (IL-10:HFc) can transduce other cell lines. The specification, however, does not teach or suggest expressing *only* IL-1beta, tumor necrosis factor or PDGF (rather than a fusion) in ARPE-19. Thus this prior art is neither anticipates nor renders obvious the pending claims.

### ***Conclusion***

Claims 1, 10 and 24 are rejected. Claims 10 and 37 are free of prior art. Claim 37 is objected to but would be allowable if the objection were overcome.

This is a CPA of applicant's earlier Application No. 09/559,707. All claims are drawn to the same invention claimed in the earlier application and could have been

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finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

February 23, 2003



REMY YUCEL, PH.D  
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